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Norway Biotechnology Biotechnology in Food and Agriculture 2004

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Report Highlights:

Current and developing Norwegian legislation and regulations concerning bioengineered food and feed products coupled with negative public sentiment and a generally protecionist environment make their sale in Norway a dim near-term prospect.

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EXECUTIVE SUMMARY

Although biotechnology food and feed product questions and issues are perceived to be controversial in the Norwegian marketplace, the absence of discussion is much more striking than its presence. Apart from small sectors in Norwegian society that include certain members of the scientific community and the various government agencies, Norwegians in all sectors have let it be known that bioengineering is so unwelcome that it is fair to say the questions are not even being asked.

While there is no general ban of GMO products in Norway and the 1993 Gene Technology Act and the Norwegian Food Law provide the primary and basic legislation for their regulation, approval and labeling, only four products have actually received approval for marketing in Norway (one line of tobacco and three lines of carnations). However, none is currently grown in or imported into the country. New regulations -- both those conceived domestically and those intended to harmonize new EU regulations -- continue to be introduced and implemented, with the likely effect of increasing restrictions even further in the near future. The implementation and integration of this new Norwegian legislation and the lifting of the several year moratorium on GMO approvals at the EU level make understanding the regulatory process a continually changing challenge.

While Norway is not a member of the EU, it is a member of the European Economic Agreement (EEA). This relationship obligates Norway to follow EU food safety standards, unless they directly contravene Norwegian law. Through the adaptation of the EEA agreement, Norway has the authority to reject any EU-approved GMO that does not meet the requirements of its domestic gene technology legislation and it has done so in at least eight cases in the recent past. Here, as will be critical in the approval process, it is important to differentiate between living organisms and processed foods. In Norway, only EU legislation concerning GMOs -- the living organisms -- is implemented, not the EU legislation for GM food products. However, there is an ongoing process evaluating a possible implementation of the EU legislation on GM foods in Norway.

The reasons behind Norway's official reluctance to accept either living GMOs or modified products are multi-faceted. One prevalent Norwegian attitude can be summarized by the statement "prove to me why I need this and how I will benefit." This innate skepticism or conservativism may help explain the reason that bioengineered medical products like insulin and vaccines are accepted but genetically modified tomato paste, for example, is not. As one person put it, "tomato paste is not a life or death issue." So, in spite of the fact that many unknowns exist with all foods and there is no convincing scientific argument against the safety of GM foods currently being marketed by the U.S., Norwegians demand an exceptional level of certainty when it comes to GMOs and food.

Another explanation of Norwegian reluctance to accept genetically modified organisms and foods containing bioengineered ingredients may be understood within the context of the "multifunctionality" of agriculture. This refers to the non-monetary, non-marketplace importance and benefit of a strong domestic agricultural industry. Norwegians believe agriculture involves more than the production of commodities for sale on global markets; they see domestic agriculture as a central pillar of rural development, biodiversity, national culture and public welfare. This attitude continues to affect not only the Norwegian consumer but also the politicians and their policies. Norwegians of all ages and all political stripes feel that food security (through maintainance of a certain degree of self-sufficiency) is an important and relevant issue and many are willing to pay the additional costs to support this policy.

Another characteristic that may explain Norwegian skepticism about biotechnology is the fact that Norway perceives itself as a young country, having received its independence from Sweden in 1905. There are strong feelings of still-newly-found independence and pride in things Norwegian. Plus, Norway's recently acquired petroleum wealth -- owing to discoveries along its continental shelf in 1965 -- has provided the Government with the financial luxury of not having to alter its financial commitments in the form of subsidies or price supports to farmers and has lulled the country into relative inaction when it comes to changing its attitudes toward new food or feed technologies.

This broad context helps explain the reasons that imported GM foods and feed are viewed as undesirable, in spite of the fact that they do not threaten any domestic Norwegian industry. Norway has made some controversial economic decisions as in the case of the resumption of the sale of whale meat, the culling of wolves to safeguard farm animals and the exploration for and development of the petroleum industry in environmentally sensitive areas, showing evidence of its willingness to ignore the international community when its own economic interests are at stake. However, in the case of GM products, resistance is based on a completely different and predominantly non-quantifiable rationale. Herein lies the challenge for opening the Norwegian market to bioengineered agricultural products, in the event that the legislation permits it.

THE APPROVAL PROCESS

Introduction

The approval process for genetically engineered products in Norway is regulated both internally by one main and several additional Norwegian pieces of legislation, which originated in the Norwegian Parliament, and is influenced from the outside by directives originating from the European Commission in Brussels. The approval legislation on GM products is divided into two parts. One is the Norwegian legislation called the "Act Relating to the Production and Use of Genetically Modified Organisms," also known as the Gene Technology Act (GTA) of April 2, 1993. This act is comprehensive and provides the basis for approving living GMOs, plus general provisions about marking the products that consist of or contain genetically modified organisms. (See document appendix) The other part entered into force on January 1, 1999, and outlines the approval requirements for GM and other novel foods. This regulation is included in the Norwegian Food Law. GM foods containing living organisms (e.g. unprocessed soybeans or fresh tomatoes) are not covered by the authorization demand in Norwegian Food Law but, rather, by the Gene Technology Act.

When it comes to approvals of GMOs, there is one ministry with regulatory responsibility, the Ministry of Environment. In addition, the Directorate for Nature Management in Trondheim and the Norwegian Food Safety Authority (Mattilsynet) in Oslo and the Biotechnology Advisory Board are particularly influential. The complicated approval process can be broken into several paths. The distinguishing feature is whether the genetically modified organism is living or non-living. If it is living and can be field tested in a deliberate release situation (as in modified flowers or a field crop like corn or tomatoes), it falls under the authority of the Ministry of Environment for the marketing aspects and under the Directorate for Nature Management for the field tests. If it is living but kept in strictly contained facilities (like labs, greenhouses and bioreactors), it falls within the authority of the Ministry of Health. Lastly, if it is a produced food product made with a modified ingredient and is, as such, in the "non-living" category, it falls within the authority of the Norwegian Food Safety Authority. Ingredients for GM feed that are not already processed, like whole soybeans or whole corn

kernels, are considered to be living organisms and, as such, fall under the authority of the Ministry of Environment.

Table One: Authoritative Body and Areas of Responsibility

	Area of Responsibility
Ministry/Authority	
Ministry of Environment	Approval for the marketing of genetically modified living organisms that will involve deliberate release; approval for genetically modified living organisms for food and feed
Ministry of Health	Approval for contained use of genetically modified living organisms
Directorate for Nature Management	Approval for the field testing of genetically modified living organisms
Norwegian Food Control Authority	Approval for food products produced from a genetically modified organism but not consisting or containing living GMO

Living GMOs

For those wishing to obtain approval to field test or import and, presumably market, a living organism such as genetically engineered seed, the path starts at the Directorate for Nature Management (DN). An application is submitted to the Directorate, which sends it out to a public hearing and begins the process of risk assessment. DN chooses one, and sometimes more, authorities to provide input on the acceptability of the application and the credibility of the science therein. Among these authorities is the Norwegian Food Safety Authority which provides an opinion concerning food and feed safety. This opinion is based upon a risk assessment performed by an independent scientific committee. DN's experts would weigh in on environmental issues; the Biotechnology Advisory Board would provide advice concerning ethical issues, sustainable development and social benefits. After receiving the comments and recommendations from these various authorities, the DN does one of three things. If it is a field test case. DN itself makes the decision to approve or reject. In other situations, it either makes a proposal to the Nature Management Department of the Ministry of Environment or it may request additional information and/or clarification from the applicant. If it wants more information, a consultative process is begun between the authority and the company that filed the application with the intention of resolving the authority's questions. If the DN is ready to make a proposal, it differentiates between applications to which it is bound via its political membership in the EEA and applications that come from a non-EEA/EU source, like American applicants for instance. In the EEA/EU case where the item has already been approved in Brussels, the DN and the Ministry of Environment send notification to the Government, which meets every Friday, for its pro forma approval and they send a notice to the Norwegian media that a particular product has been approved. If the DN proposes to reject an EEA/EU application, it must publish a "regulation" and not a "proposal." The Ministry of Environment consults with the Ministry of Health, the Ministry of Agriculture, the Ministry of Foreign Affairs and the Ministry of Trade and Industry to derive a consensus position to prohibit the EU product, as is required under the EEA agreement.

If the applicant is an American company, for instance, submitting the dossier to Norway for approval in the EU/EEA-area or in Norway only, the procedure is quite similar but there is no legal requirement to publish a regulation. The DN can simply send its recommendation either for acceptance or rejection to the Ministry of Environment, which issues the final decision. According to the Ministry of Environment, there have been eight products that

have been rejected and for which regulations have been written. They are as follows: chicory, three strains of oil rapeseed, one strain of maize, a test kit with bacteria and two pharmaceutical products that contained living virus vaccines -- one for pigs and the other for rabies. Because each of these applications originated from the EU, a formal rejection and explanation was required, the rationale for each of which (except the test kit) is contained in documents listed in the Document Appendix of this report.

Currently, the only pending applications for living genetically modified organisms are from EU countries. Three of these applications are for lines of corn and one is for a line of soybeans. None of these applications is particularly active at this time.

Non-Living GMOs

The second avenue in the approval process is for those products that do not contain living organisms – corn oil, for instance. In this case, it is the Ministry of Health that has the legal authority for approval or rejection and it has formally delegated this responsibility to the Norwegian Food Safety Authority (Mattilsynet). An application is submitted to the Authority, which conducts a risk management assessment and either provides or denies consent for the processed product. An independent scientific committee conducts the risk assessment in order to evaluate human and animal health risks. On a practical level, there have not been any such products approved for sale in Norway, neither are there any applications currently under evaluation by the Authority.

Changing Approval Regulations

On April 18, 2004, the EU implemented Regulation 1829/2003 on Genetically Modified Food and Feed, and Regulation 1830/2003 on Traceability and Labeling of Genetically Modified Organisms and the Traceability of Food and Feed Products produced from Genetically Modified Organisms. As of this date, any food or feed product produced with GMOs must be labeled. The threshold for adventitious (unintentional) presence of approved GMOs in food is set at 0.9%, meaning if the accidental GMO presence in food is above 0.9%, the product must be labeled as containing GMOs. The threshold for adventitious presence of GMOs which are not yet formally approved but which have received a positive EU risk assessment is 0.5%. If a product contains a GM ingredient on purpose, that product must be labeled, even if the presence is undetectable, or detectable and below 0.9%.

While it is not yet clear what in the Norwegian legislation itself would have to be changed, the Norwegian authorities is moving in favor of integrating these new policies, given their natural preference for increasing restrictiveness concerning both living and non-living GMOs. There appears to be wide-spread support for a formalized traceability process. In terms of practical application for the approval process (labeling and traceability will be dealt with in the next section), the most significant change anticipated in Norway by the new EU regulation is that the end to the moratorium on approvals in the EU could, in turn, mean an increase in the number of applications submitted to the Norwegian authorities. However, in the event that these new applications do not meet Norwegian approval standards, the applications will be rejected according to the Gene Technology Act and the Norwegian Food Law.

With the EC Directive 2001/18 on deliberate release genetically modified organisms (GMOs) into the environment, there seems to be an increasing tendency for the EU approval process to take into consideration the kinds of criteria that the Biotechnology Advisory Board applies to Norwegian approvals. Those considerations include sustainability, social benefit and ethics

(see Document Appendix). While the Norwegian Biotechnology Advisory Board has applied such subjective and ill-defined standards for quite some time, the fact that new EU legislation has taken these concerns into consideration is something that has received broad praise in Norway. It should also be noted that on March 4, 2002, new Norwegian legislation, resulting from a 1997 Parliamentary decision, that totally prohibits GM food and feed with functional antibiotic resistance genes entered into force.

LABELING, TESTING AND TRACING REQUIREMENTS

GM food and feed products produced in or imported into Norway must be labeled according to a parliamentary decision from 1995. Labeling requirements are contained in both the Gene Technology Act (paragraph 15) and in the Norwegian Food Law. The Norwegian Food Law includes regulations on labeling of GM foods and feeds. The Norwegian labeling requirements on GM foods entered into force in October 1997, and apply to all GM foods including genetically modified organisms (GMOs) and food derived from genetically modified organisms, regardless of whether their properties or characteristics are different from those of comparable conventional food. The purpose of the labeling, according to various interviews sector-wide, is to meet consumers' demand to know if the product has been derived from genetically modified organisms, thus enabling them to make an informed choice. The labeling requirements are considered to be satisfied if products containing genetically modified ingredients are labeled as such if the genetically modified component constitutes more than two percent of the ingredient. Norwegian labeling requirements on GM feed entered into force in 1999.

Norwegian labeling is required on GM food regardless of whether the DNA or protein is present. In other words, even though it may be impossible to test for its presence or absence, it must be labeled. The new EU regulations represent a harmonization with the Norwegian standards as regards to labeling. For the past seven years, Norway has also required process labeling for GM products indicating that the product is derived from GM food techniques, even though there may be no evidence of it.

With no scientific methods to validate that the product is GMO-free when no DNA protein is present, the authorities must implement and depend upon quality assurance systems including documentation control that identifies GM products or, more accurately, GMO-free products. This is where tracing and testing come in. While Norway has no regulations on traceability, most industry and trade have internal control standards in place that both promote quality along the food chain and assure the authorities that the regulations are being followed. These should also include systems to prevent non-approved GM products from being manufactured. The Norwegian Food Safety Authority perform inspection and random testing of feed, seed and food all along the supply chain. The samples are analyzed by the National Veterinary Institute, which is the enforcement laboratory for GMO analyses.

Where analytical methods are not available or are not sufficiently sensitive, the authorities rely on documentation control. However, no specific regulation about the kind of documentation that is needed to demonstrate that the presence og small amount of GM material in a non GM product is adventitious and technical unavoidable. The Norwegian Food Control Auhtority is working on guidelines about what is acceptable.

For instance, soy marketed as non-GM may contain traces of Round-up Ready soybeans (RRS), despite extensive efforts to prevent contamination. Therefore, Norway has established an enforcement practice where approval of foods with "unavoidable traces" of GMOs is not considered necessary. However, the quantifiable definition of "unavoidable traces" may vary over time, depending upon The Norwegian Food Safty Authority's

evaluation of what levels are "reasonable" and "satisfactory." The currently applied management practice is that the Authority will tolerate maximum levels up to 0.5% for GM and GMO that among other things, have positive risk assessment in EU or Norway but are not yet authorized and 0.9% for GM and GMO that are authorized in EU, provided that the supplier, producer and importer of a food product can demonstrate that measures have been carried out.

Since 1999, Norwegian legislation permits the import and use of GM feed (but not GMO), if it is labeled according to the legislation. Prior to 1999, this was an unregulated area. The Norwegian Food Control Authority has responsibility over imported and nationally produced feed and performs random tests. In 2001, 1,100 samples of imported feed materials and nationally produced feed were taken. About 85 of them, all products containing corn or soy, were tested for GMO content. Of those tested, none was found to contain GMOs or GM material above the labeling threshold; thus none needed to be labeled. However, the Service did detect some traces and contents in the category of less than two percent. If these traces are found in whole corn or whole soybeans, the Authority handles this matter on behalf of the Ministry of Environment, which has approval authority over living GMOs. Currently, labeling is required on genetically modified products and packaged items, for instance ketchup and boxes of genetically modified tomatoes. Upcoming changes will be made in accordance to the new EU directives. These changes will be notified to WTO in the autumn of 2004.

The Norwegian consumer is currently requesting increasing amounts of information on food products in order to make an informed choice and this demand sometimes goes beyond the requirements of the EU. There is concern about where a product was raised -- do sheep graze on lands that were affected by the Chernobyl disaster? Are crops -- even those designated as organic -- grown in a particularly polluted part of the Ruhr valley? Are chickens or cows penned or do they roam freely? In these cases, Norwegians are asking for -- and receiving -- information not just about the product but also about the processes by which an item becomes a product. The question of whether this increased information actually influences purchasing patterns will be addressed later in the section on the Marketing Environment.

Although it is fair to say that the predominant focus of product labeling has been for items destined for human or animal consumption, there is pending Norwegian legislation (that is expected to be approved in the fall) that would require labeling of GMO non-food items. This regulation would apply to, for instance, the three lines of GM carnations and the one line of tobacco that have already received approval but have not yet been imported to Norway for sale or distribution. In addition, it is worth repeating that this evolving and intricate system of labeling -- internally in Norway and externally by the EU -- is hypothetical since there is no genetically modified food allowed in Norway.

THE MARKETING ENVIRONMENT

Consumer Opinion and Awareness

There are two main consumer organizations in Norway which are useful in gauging attitudes about biotechnology and GMOs. One is the Forbrukerrådet or The Consumer Council of Norway while the other is the Statens Institutt for Forbruksforskning or the Consumer Research Council. The Consumer Council is charged with formulating opinions concerning consumer policies and to assist consumers when they have consumer-oriented complaints. The Consumer Research Council conducts research with an emphasis on practical results that

can support consumers' position in the market and to increase the public authorities' knowledge about consumer issues.

Issues concerning biotechnology and GMOs are subsumed under the general category of food safety, an issue of high priority in Norway. While there is evidence of a divergence between attitudes expressed by consumers in surveys conducted by the Consumer Research Council and the reality of their consumption patterns, it was confirmed that biotechnology in general and genetically modified products in particular are thought of as "food hazards." (See "Trust in Food in the Age of Mad Cow's Disease," English language summary, pp. 15:22, listed in Document Appendix.) Norwegians associate biotechnology with highly advanced industrialized agricultural practices implemented and controlled by big industry and multi-national corporations. Not only is this type of farming perceived to be non-existent in Norway but it is also highly undesirable. The Norwegian reality includes the practive of both large and small-scale farming. In addition, while highly subsidized, expensive and dependent upon protection against imports, agriculture continues to play a role beyond that of strict economic importance to the country. But, attitudes are changing slowly. While public support has continued to make it possible to subsidize small farms up in the mountainous areas of Norway, the subsidies have been reduced as a result of international WTO agreements. Public support for the Farmer's Party, now called the Center Party, has declined as has the support for the Social Democrats, Christian Democrats and Left Party -each of which is viewed as strong supporters of Norwegian multifunctionalism. In spite of these trends and the fact that the multifunctionalist notion forms an integral part of Norwegian policy at the district level, biotechnology -- in contrast -- is seen as something at the other end of the spectrum. Moreover, during the past seven to ten years, the number of skeptics has increased to 70 - 80 percent of the population, which may explain the reason that the topic is not even debated in communities outside those that conduct research and development.

The public's level of knowledge and sophistication about biotechnology and bioengineered products is rather limited. While the few advocates in the scientific community give occasional interviews to the press, there are prominent and vociferous detractors in the scientific community -- as well as elsewhere -- whose access to the media and impact on public opinion is acknowledged to have great influence. The public's skeptical attitude is explained as the result of high profile coverage of food safety scandals, some but not all of which are biotechnologically related. For instance, in the late 1990s, the debate on genetically modified salmon being tested in Canada was played out on the front pages of Norwegian newspapers and presented as "monster salmon." One scientist described a contentious situation that arose at the official dedication of the new biotechnology building at the Agricultural University in Ås earlier two years ago. Her address included the prospect that genetically engineered fatty acids could be used to stem the decreasing supply in fish food, an important Norwegian domestic and export product. This, in turn, prompted a major media debate. As a result of increasingly high profile coverage by the Norwegian and European media of innumerable food scandals from BSE to dioxin to foot and mouth disease to monster salmon, surveys and focus groups have shown that "contentious" consumers are fed up with these notions of modern food science and have hunkered down with attitudes of near total rejection.

The Norwegian Government has been able to shelter the Norwegian consumer from having to make rational economic choices about agricultural policy, in part due to the discovery of petroleum along the Norwegian continental shelf in 1965 and the subsequent revenue accruing to the Government from its sales. In spite of this, however, that which the Norwegian consumer says in surveys and focus groups and that which s/he does in practice are, in many instances, two separate things. A growing quarter of Norwegian consumers is enticed across the border to Sweden by cheaper (although perceived to be of as high or

higher quality) goods -- particularly meat, cheese, alcohol and tobacco. Thus, there seems to be some elasticity when it comes to the price of food. It should also be noted here that, although Norwegians leave Norway for these purchases, they are still purchasing items in an EU country and, thus, food safety concerns are regulated by most of the same legislation that has been harmonized in Norway.

The level of trust between the Norwegian consumer and the regulatory authorities is extremely high. The ministries of agriculture, environment and health along with the Norwegian Food Control Authority have established a significantly high level of trust between consumers and themselves. This trust does not extend to producers or retailers, as it is believed that market forces alone will not produce safe, healthy food. According to the National Institute for Consumer Research's report entitled "Trust in Food in the Age of Mad Cow's Disease," two-thirds of Norwegians presume that information provided by environmental organizations is somewhat exaggerated and only nine percent have full trust in the information on food scandals that is presented by the media. Most consumers believe that the farmers and the grocery trade and food industry representatives would not tell the truth, if there were to be a food scandal in Norway.

Farmers' Unions

There are two farmers unions in Norway and they are divided by the political orientation of their membership. Norges Bondelag is the more traditional of the two groups and many of its members support the Center Party which used to be known as the Farmers Party. Their membership of approximately 60,000 is comprised of 34,000 large and small farmers, with the remainder being students, agriculture professionals and members of the general public. The other union, whose membership ranges between 5,000 to 10,000, has as its political orientation a more red/green socialist affiliation. This second union's farmers are all small farmers. In an annual spring exercise resulting in intervention at the national level in the agricultural sector, both farmers' unions and the Government negotiate the level of subsidies to farmers and price controls for their products. While the Norwegian political system assigns this central role to the national government, districts also have some independence when it comes to the support of farmers.

Farmers have, in general, not been particularly receptive to new farming techniques, neither organic ones nor those that might incorporate genetic engineering applications. Norwegian farmers are described as, by and large, traditional and conservative and would not be likely candidates to agitate for changing the status quo, unless they were to see some direct financial or qualitative benefit from that change.

Food Retail Sector

The Norwegian food retail sector is comprised of four main players. None of these major retailers has much incentive -- either legally or financially -- to take the lead in introducing genetically engineered products, if there were ever to be any approved, into the Norwegian marketplace. This stems from two main factors: (1) consumer reaction is perceived to be critical and (2) media reaction is also perceived to be predominantly negative. In order for the sale of a genetically modified product to be successful, these anticipated negative responses would have to be offset by either a significantly lower price for the same quality good and/or evidence of greater sustainability, social benefit and ethical development. Given that approximately one-quarter of the Norwegian population travels across the border to Sweden in order to purchase cheaper meat, cheese, tobacco products and alcohol, there is evidence of price elasticity on consumer purchasing patterns. These trans-border purchases account for approximately ten percent of the consumer market's total.

Norwegian food retailers are keenly aware that the European food scandals of the 1990s have increased the levels of frustration of the Norwegian consumer and that Norwegian consumers want proof of quality. This is one of the reasons that documentation from suppliers is so important to the retailer. In the event that random tests cannot or do not validate food safety, the perception is that the documentation system does, even though it cannot provide guarantees. Encouraged by increasingly influential print and electronic media that bring food safety issues to the receptive public's attention, retailers are approached by consumers and critics when there are any perceived problems. At that point, the retailer can turn to its numerous suppliers and producers to request quality assurance certificates and attempt to rectify the problem. Retailers include in their contracts with their suppliers an assurance that they will guarantee (and label) any product with a modified ingredient of more than two percent. Retailers conduct random tests of the products they sell. In the event of a questionable result, they have and do pull products off the shelves. However, in most cases where there is a questionable result, the retailer, the supplier, SNT and MATFORSK (the Norwegian Food Research Institute) work cooperatively to obtain an explanation and to resolve the problem out of the limelight. Testing, of course, contributes to the high price of food in Norway although Norwegians spend only 12% of their household budgets on food, compared to their EU neighbors who spend approximately 15%.

The possibility of a future replete with genetically modified raw materials and products is of great concern to long-range company profitability. However, this concern does not appear to be coupled with a long-term strategy for dealing with or resolving the issue. Many in the retail and production sectors view this future scenario as presenting tremendous challenges (not opportunities) for Norway from the ministerial level on down to the consumer. While the recent centralization of the Norwegian inspection authorities as well as the increasing sophistication of tests is believed to facilitate responsiveness and access to information, it is clear that concern about "stemming the GMO tide" lurks just under the surface for both retailers and producers. It remains to be seen how the system will want to and be able to respond to the increasing spread of genetically modified primary ingredients.

The Norwegian feed manufacturing sector includes the import of soybeans for soymeal, crude oil and refined oil. The meal and crude oil is used in compound feeds, mostly for animal consumption. Until 1997, Norway's sole soybean crushing company, Denofa, imported half of its requirments from the United States, with the rest coming from South America. The change came in 1997 when some of its main customers who manufactured butter substitutes heard about GMOs and did not want them in their products. Denofa tried to convince the U.S. suppliers to eliminate their genetically modified soybeans (rather than to try to convince their customers of the safety of the product) and, when that failed, the company eliminated U.S. soybeans from its supply. At that point, however, it should be noted that Denofa did not really know whether the soybeans were -- or were not -- genetically modified.

After Denofa moved away from U.S. suppliers, it turned for two growing seasons to Canada, where Round-up Ready soybeans were not yet widely in use. After the spread of genetically modified soybeans across Canada, Denofa moved its procurement to Brazil, where they were able to purchase significant amounts of land and control the growing, harvesting, transportation and shipping process from farm to their processing plants in Norway. Given that genetically modified soybeans are classified as living organisms, there is a zero percent tolerance, according to the 1993 Gene Technology Act. The company was able to provide its guarantee for GM-free soy products as a result of an extensive internal control system that tests for the presence of GMOs in the seed, in the plants during the growing season, on the trucks that take the beans to the silos, in the silos, in the containers and at their processing

plants. More recently, however, Denofa has moved away from contract growing on few large farms in Matto Grosso to procurement from a variety of smaller farmers in the region. This was due to the price demands being exacted by their farmer contractors. Inspection done at Denofa's receiving warehouses in Matto Grosso prior to purchasing are indicating an increasing presence of bioengineered varieties from supposedly GM-free fields in this area and, as a result, increased rejections of truckloads of soybeans by Denofa. The company provides a closed system for which their customers are willing and do pay a premium. Because the company is of a relatively small size, it was able to make a business decision about five years ago to grow and process only GMO-free soybeans. Denofa has expanded its crushing capacity to about 400,000 MT to accommodate and expanding market for their soy products. Their market has grown to include 30,000 to 40,000 tons of meal for pet food and an additional supply to Nestlé, both of which the company representative attributes to the company's commitment to GMO-free soybeans.

As long as there are customers willing to pay a high price for these goods, the prospects for this company, and its GMO-free soybeans, are good. Although half of the meal is sold to the domestic market, half is shipped to a Europe that may be increasingly open to the presence of GMOs. Given that European companies have quite a choice of soybean product suppliers, the risk of an increasingly smaller market for their higher priced goods is a realistic long-range concern. Additionally, Denofa's more recent difficulties in procuring GM-free soybeans from Brazil have spurred Denofa to lobby for an increase in Norwegian tolerance levels.

Another policy decision that will affect the feed market is that, from July 2002, Norway opened its markets to feed product imports from the least developed countries. Given that Norwegian law will govern imports grown in environments with different uses of pesticides and, potentially, GMO seed, it remains to be seen how this will play itself out.

Food Processing Sector

The Norwegian food processing sector is dominated by one company called Orkla ASA, which is a conglomerate of many other companies. It is one of Norway?s largest listed companies and has annual sales of more than USD 4 billion. The three areas of concentrated activity include branded consumer goods, chemicals and financial investments. Approximately 60% of the Group's 18,500 employees are employed in Norway. With annual sales of approximately USD 3 billion, branded consumer goods is Orkla's largest area of activity. Orkla Foods itself is divided into seven divisions: Stabburet, Procordia Food, Beauvais, Felix Abba, Orkla Foods International, Abba Seafood and Orkla Food Ingredients. The company is a leading developer, producer and marketer of pizza/pies, sauces, snacking products, ready meals, fruit and berry products, pickled vegetables, seafood, potato products and baking ingredients. Sixty percent of these products are sold to the grocery market under Orkla Foods' own brands, with the catering sector, the food industry, exports and tax-free sales accounting for the remainder. The Nordic market accounts for 90% of operating revenues and is home to 31 of the company's 41 production plants. Most operations outside the Nordic region come under a separate division, Orkla Foods International and the company is looking to southeast Asia and China to expand its activities in the branded consumer goods areas, primarily food and beverages. For the purposes of entering the Asian market, Orkla operates from its subsidiary in Singapore, Orkla Asia Pte Ltd.

The company publishes two policy papers that concern modern gene technology. Orkla?s position is a restrictive one in which it is bound by national legislation and official requirements in the GMO area and is influenced by consumer attitudes. It acknowledges in

the first policy paper that modern gene technology offers greater possibilities for giving plants, animals and microorganisms new properties and by transferring genes between organisms which have traditionally been unable to exchange genetic material, it is possible to create genetically modified organisms (GMOs) with new properties that simplify cultivation and breeding or provide improved end products for consumers. However, Orkla has a restrictive policy regarding the use of modern gene technology in the production of food because a clear majority of consumers in its main markets do not accept the use of genetically modified raw materials. (From Orkla ASA "Policy on Modern Gene Technology," adopted by the Orkla Group Executive Board on 17 December 2001.)

In an attempt to clarify Orkla's policy on GMOs, the "Policy on the Use of Modern Gene Technology in the Production of Food," paper, also from 17 December 2001, states that this approach applies to all Orkla's food producing companies with respect to raw materials and products that are to be used in the production of food. It elaborates with six points. First, the food companies are to use raw materials, ingredients, additives and flavorings that are based on traditional production methods. "Traditional production methods" are defined as methods whereby the plant, animal or micro-organism is produced, developed and improved without the use of modern gene technology. They are to have adopted a restrictive policy regarding the use of modern gene technology in the production of food. If a food company is considering marketing and selling products that require GMO labelling, this matter must be discussed by the Board of Directors of the business area concerned before a decision is made. The food companies are to be responsive to the attitudes of customers and consumers to the use of modern gene technology in the production of food, and comply with national legislation and official requirements in the GMO area. They are to require suppliers to establish verified systems for separation, documentation and analysis in order to make it possible to assure the origin and quality of products, for example the absence of contaminating GMO material. As far as technically possible and financially feasible, food companies should avoid using processing aids (including enzymes which are classified as processing aids), extraction agents or solvents that are produced with the help of modern gene technology, even though the end products do not have to be GMO labelled. Similarly, the food companies make efforts to avoid the use of substances originating from micro-organisms that have grown on substrates containing material from genetically modified organisms. Lastly, food companies are to support suppliers in their efforts to supply raw materials, ingredients, etc., which come from animals fed on feed that is produced using only traditional production methods.

Orkla states that it is monitoring developments, both with respect to customer and consumer attitudes to modern gene technology and with respect to the potential and hazards that new genetically modified organisms may present in the future and, if Orkla is to change its restrictive policy on the use of modern gene technology, raw materials and production methods that are based on such technology must: (1) have proved to be safe from the point of view of health and the environment, (2) be accepted by large customer and consumer groups and (3) lead to products that offer significant advantages for customers and consumers.

Biotechnology Advisory Board

The Norwegian Biotechnology Advisory Board, authorized under the 1993 Gene Technology Act, is an independent body consisting of 24 members plus six observers. Members are chosen from eight different organizations across Norwegian society: one trade union representing the employers, one representing employees, the National Research Council, an organization representing the handicapped, the Consumer Council, non-governmental organizations (including environmental organizations), one of the two farmers' unions (they

switch off) and one of the two fisheries organizations (they also rotate). The six observers, who may ask questions and make comments but not vote, represent six different government ministries: Agriculture, Fisheries, Health, Commerce, Environment and Administration. The Advisory Board has the responsibility for coordinating responses on health issues during the approval process as well as for issues of sustainable development, social benefit and ethics. Its advice is targeted at the Ministries of Health and of Environment, in particular, and, while there is no formal advisory role with SNT, a close working relationship exists. Because its members are chosen for their personal skills and scientific background and are often engaged in public debate, they are frequently brought in on the GMO issue when members of the Norwegian Government meet with their EU counterparts. The Board advises the Government about questions it should ask of the EU in an attempt to influence the legislation and to obtain clarification on various points of concern. Once the EU has made a change in policy, the Norwegian Government has thirty days to either approve or reject it. The Board perceives itself to be quite influential due to its expertise.

In terms of the Board's decision-making process, it provides recommendations and not consensus decisions. Individuals and groups sign particular position papers and these differences of opinion are forwarded as such to policy makers. A split decision in early 2000 about an application to approve genetically modified blue carnations provides an illustrative example. The Board took split positions concerning the sustainability of blue carnations, as it found it easy to argue that blue carnations are not socially beneficial. However, this decision was extremely difficult to quantify. (See attached document in Norwegian of guidelines from the Biotechnology Advisory Board for work in this field. These guidelines are also used by the Ministry of Environment and the Directorate for Nature Management.) Thus, while agreement was reached about the lack of social benefit, one group accepted the idea of approval while the other did not. Ultimately, the Ministry of Environment approved the application, (at the time of the approval, the carnations would not have to have been labelled as being genetically modified because they are not for human consumption) but, to date, they have not been marketed in Norway.

While the Biotechnology Advisory Board used to concentrate its GMO expertise in the fields of health and even environmental risks, it has recently broadened its focus to include ethical and social issues. Norway has been out in the forefront on these types of considerations and, believes has effectively influenced the adoption of these types of considerations by the EU. Environmental Groups

Three main environmental groups in Norway are: (1) Naturvern Forbundet (Nature Protection Society), (2) Natur og Ungdom and (3) Bellona. While environmental groups have suffered a series of defeats recently -- including in the areas of petroleum extraction, whaling and wolf culling -- they do not seem to have biotechnology issues high on their agenda. One reason for this attitude may be explained by their view that the general population is in solidarity with their cautious position. Thus, there is not really any battle to fight in Norway concerning these issues and they direct their efforts to more domestically contentious problems.

RESEARCH AND DEVELOPMENT IN NORWAY

When evaluating the research and development activities in the biotechnology area in Norway, it is important to examine the fields of research and the type of governmental support. It appears that there is quite a bit of research being conducted in order to "safeguard the country from GMOs." Risk assessment techniques are being developed that will produce testing systems to facilitate the detection of genetically modified organisms with

increasing sophistication. It is here, however, within the scientific community, both at the university and at the policy level, that there appears to be the most activity on the GMO front.

Several reasons underlie this activity. Firstly, because of the increasing use of GMO technology worldwide, Norway's scientific community needs to have the competence to judge that which is happening in the field. This is important in order to enable the scientific community to make informed decisions. The Norwegian scientific community wants to ensure that it is not left behind. Another reason identifies the possibility of a shift in attitude by the general public and, in particular, a radical and sudden shift. With the global geographic area of GMO production already larger than the whole area of Norway, members of the research and development community more readily and realistically prepare for the eventual presence and even acceptance of GMOs in Norway in a way that is more proactive than that which is found in most other segments of the population.

Several new research programs have been established that have biotechnology components. One, with several biotechnology projects, is called "Biologisk mangfold, dynamikk, trussler og forvaltning." Another is "Etikk, samfunn og bioteknologi." The Ministry of Health and the Ministry of Environment support the newly established "Institutt for genokolgi" in Tromso, which does research on the health and environmental effects of gene technology. The National Research Council has, within the past few years, funded the FUGE or functional genomics project to the tune of NOK 100 million. This program, which commenced in 2002, but with funding for five to ten years, has its own board and is independent of the National Research Council. The program was funded for three reasons. It was stated that basic research has totally changed as a result of advances in gene technology and it is important for Norwegian institutions to be part of that changing reality and not be left behind. There have also been advances in medicine as a result of genomics that have been widely beneficial and accepted in Norway and this type of research needs to be supported. Lastly, the importance of the Norwegian fishing industry requires scientific participation in changes in aquaculture and marine science.

The implementation of FUGE was credited to what have been described as "major changes in attitudes over the past year or two, even at the political level." On June 5, 2001, the Prime Minister took the initiative to host an international conference at the University of Oslo on biotechnology and the implications of a biotech society. The conference drew a crowd of several hundred participants and received "pretty positive" press coverage. In addition to the FUGE program, the National Research Council supports, among its six different areas of interest, programs that examine the genome of salmon (funded at NOK 10 million yearly (about US\$ 1 million)), the identification of genetically modified proteins and genes (with consideration given to soy protein) and the ethics of research.

Other evidence of activity and ongoing research and development in the field of biotechnology in Norway can be found, for example, in the new biotechnology building that opened two years ago at the National Agricultural University. It now houses members of the chemistry, genetics and microbiology faculty. But, while the climate for biotech research may be seen to be improving over the recent past, work on GMOs is done somewhat surreptitiously and without drawing attention to itself. As a matter of fact, while the National Research Council will fund certain biotechnology projects, those openly containing GMO aspects are bound to "run into hassles" at the approval level. Scientific research into GMOs -- both living and non-living -- is governed by the same approval process as is discussed above. For experiments dealing with living GMOs and for which deliberate release and field testing is part of the research proposal, approval must be sought according to the Gene Technology Act from the Ministry of the Environment. For research on non-living GMOs or

those which would be tested in laboratories and greenhouses, the Ministry of Health and the SNT determine the approval.

It should be emphasized that several members of the scientific community expressed the idea that Norway cannot afford to be left behind either the rest of Europe or the rest of the world as others continue to make advances and discoveries in the field of GMOs. That is an attitude acknowledged not only by the European Commission but also by quiet but powerful players within the Norwegian production sector. This researcher learned of a professor at the Agricultural University whose current research with lactic acid and microbes includes genetic modification -- something that is understood but not openly discussed by the dairy monopoly for fear of bad press and negative consumer reaction. However, the diary industry continues to support this type of research that will permit it to be a player in a changing market, if and when that happens. That having been said, this researcher spoke with scientists who have made conscious decisions to shy away from the use of GMO techniques in their research, choosing to work with gene therapy and other traditional types of biotechnology techniques rather than run the risk and hassles of confrontation with authorities, the media and public opinion. However, this is one sector more receptive to GM technology and should continue to be carefully monitored for changes.

OUTLOOK FOR THE SALE OF GMOs ON THE NORWEGIAN MARKET

In order to assess the outlook for the sale of GMOs on the Norwegian market, it is important to differentiate between short- and long-term potential, as each tells a completely different story. In the immediate future, increasingly restrictive legislation concerning tracing and labeling as well as other regulations on zero percent tolerance of antibiotic resistance genes already in place, making the possibility of a liberalization of attitudes legally more difficult. The increasing emphasis upon "soft" criteria in the production and labeling process will also complicate any import potential. Harmonization with the EU -- in some cases where restrictive Norwegian recommendations have influenced EU legislation -- will also limit the liberalization prospects in the short term. However, in the long term -- and that may be for a period of between ten and twenty years in the future -- the continuation of restrictive attitudes will likely be tempered by the growing reality of a world increasingly filled with engineered crops and a decreasing probability of limiting their introduction, development and growth into both the Norwegian and the even larger European market. A sustained long-term engagement with the scientific community and a transparent public relations campaign about genetically engineered products with clear, direct benefit to consumers provided at a lower price than the traditional product could go a long way to change Norwegian attitudes and, ultimately, legislation. However, without a change in legislation, even those Norwegians whose attitudes are receptive to bioengineered products will be prevented from having access to them.

While prospects for the short term are very limited, long-term prospects are more promising and several different strategies could be successful. The first strategy would involve getting approval for and introducing a trial, successful product that contains GMO material. This product must have either or both direct qualitative superiority over an existing product or a significantly lower price. In a Norwegian radio program aired two or three summers ago, there was a report from Trondheim on a test of transgenetic strawberries. Norwegian shoppers were offered the same quantity of regular and transgenetic strawberries at the same price. While the report detailed general curiosity about the bioengineered strawberries, consumers made no purchases. However, when faced with the direct and personal financial benefit when the price on the transgenetic strawberries was dropped to half that of their traditionally grown counterparts, all the cheaper transgenetic strawberries sold. Norwegians devotion to multi-functionalism must be lapt in mind. Thus, inconsistencies apparent in

reconciling those non-quantifiable attitudes with real temptations for cheaper prices cloud the prospects for anticipating consumer buying patterns.

The last suggested long term strategy requires the application of science (and specifically genetic modification) to address the kinds of problems experienced by Norwegian farmers due to cold climate farming. If genetic modification could solve daily and seasonal problems by increasing frost tolerance or shortening the growing season of a product, particularly if there were to be a price advantage, there might be a willingness shown by some of the larger and more mechanized farming operations to apply these techniques.

While none of these strategies is guaranteed to pry open the Norwegian market to GMOs, each is bound to whittle down the steadfast determination held against GMOs that is typically found across the spectrum of Norwegian society. A sustained effort to tackle different components of Norwegian society in ways that meet their individual concerns could, particularly in an global environment increasingly penetrated by genetically modified organisms, prove successful in the long run.

SUMMARY OF CONTACTS

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